DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Interoffice Memorandum of Understanding Between the Office of Health and Industry Programs (OHIP), the Office of Systems and Management and the Office of Device Evaluation (ODE)

Procedures for Listing Medical Devices and In Vitro Diagnostic Products Exempted from Premarket Notification [510(k)] on the Internet.

Purpose: Section 211 of the Medical Device User Fee and Modernization Act (MDUFMA) amends § 510(m)(1) to require FDA to post on the Internet the list of class II devices we have exempted from 510(k), and to update the Internet posting within 30 days of any revision of the list. These same procedures are applied for the list of class I devices we have exempted.

Procedure:

1. Once a device is exempted from Premarket Notification [510(k)] through the publication of a Federal Register Notice, the Program Operations Staff (POS), in the Office of Device Evaluation (ODE), Center for Devices and Radiological Health (CDRH) enters this regulatory change in the CDRH Information Retrieval System (internal database for tracking regulatory programs for CDRH). (Please note that POS also works for the Office of In Vitro Diagnostic Devices Evaluation and Safety.)
2. On or about the 6th of each month, the Office of Systems and Management will copy the list of devices exempted from 510(k) from the CDRH Information Retrieval System to the Internet Database of Exempted Medical Devices and In Vitro Diagnostic Products on Device Advice at the following URL
   http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm
3. Subscribers to the CDRH New Items List Serve will receive an email notifying them that the list of devices exempted from 510(k) has been updated on or about the 6th of each month when a change was made. You may subscribe to the CDRH New Items List at http://list.nih.gov/archives/cdrhnew.html.
4. POS, ODE will verify that devices exempted from 510(k) within the last 30 days have been added to the updated list of exempted devices on the Internet after receiving an email from the CDRH New Items List Serve that the Internet list has been posted to the following URL as a final confirmation.
   http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm

Lireka P. Joseph, Ph.D.
Director, Office of Health and Industry Programs

Daniel G. Schultz, M.D.
Director, Office of Device Evaluation

Ruth Clements
Ruth E. Clements
Associate Director for Management and Systems, OSM